UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA, Plaintiff, v. PROPHARMA, INC., a corporation, and VICTOR G. FARINAS, REYNALDO G. FARINAS, individuals, Defendants.	)	NO. 04-22933-CIV-Altonaga/Bandstra

CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, by Peter D. Keisler, Assistant United States Attorney General for the Civil Division, and Marcos Daniel Jimenez, United States Attorney for the Southern District of Florida, having filed a complaint for permanent injunctive relief against Propharma, Inc. ("Propharma"), a corporation, and the following individuals: Victor G. Farinas, and Reynaldo G. Farinas, (hereinafter, collectively, "defendants"), and defendants having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of current good manufacturing practice ("CGMP").

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), after shipment of one or more of their components in interstate commerce.

5. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded under 21 U.S.C. § 353(b)(4)(B), in that they are not prescription drugs within the meaning of 21 U.S.C. 353(b)(1) but bear the symbol "Rx Only."

6. Defendants violate 21 U.S.C. 331(k), by causing drugs

that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

7. Defendants violate the Act, 21 U.S.C. § 331(d) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

8. Upon entry of this Decree, defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any articles of drug, as defined by 21 U.S.C. § 321(g)(1), at or from Propharma's facilities at 7760 NW 56th Street in Miami, Florida or 3307 NW 74th Avenue, Miami, Florida, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP. See 21 C.F.R. Parts 210 and 211.

B. Defendants retain, at defendants' expense, an independent person or persons (the "expert"), to make inspections of their drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement between the parties) to defendants or their immediate families. Defendants shall notify FDA in writing of the identity of the expert as soon as they retain such expert. The expert shall:

i) Perform a comprehensive inspection of defendants' facilities and the methods and controls used for manufacturing, processing, packing, labeling, holding, and distributing drugs to determine whether they are in compliance with CGMP;

ii) When appropriate, and after providing FDA with no less than five (5) business days prior notice, certify in writing to FDA that defendants' facilities, methods, and controls are in compliance with CGMP; and

iii) Submit to FDA as part of the certification a full and complete written report prepared by the expert of the results of his or her inspection.

C. Defendants cease manufacturing, processing,

packing, labeling, holding, and/or distributing OTC drug products, including but not limited to, DEKA Cough/Cold Formula, Uni-Hist DM Pediatric Syrup, DECON-DM, Panatuss DX, TUSSAFED EX, TUSSIPHEN-DM antitussive/expectorant, HISDEC Antihistamine/Decongestant products, and similar OTC products that have the "Rx Only" symbol on their labeling, and ensure that the "Rx Only" symbol appears only on the labeling of drug products that are prescription drugs under the meaning of 21 U.S.C. § 353(b).

D. Defendants ensure that those drug products that Propharma manufactures, processes, packs, labels, holds, and distributes pursuant to the FDA monograph concerning "Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use," 21 C.F.R. Part 341, are in strict compliance with the FDA monograph. Defendants shall also ensure that any drug products they manufacture, process, pack, label, hold, and/or distribute that deviate from an FDA monograph are the subject of an approved new drug application under 21 U.S.C. § 355(a) or an investigational new drug application under 21 U.S.C. § 355(i).

E. Defendants report to FDA in writing the actions they have taken to: (1) correct the CGMP deviations set forth in the Complaint and ensure that the methods used in, and the facilities and controls used for, manufacturing, processing,

packing, labeling, holding, and distributing drugs are operated and administered in conformity with CGMP; (2) correct the misbranding violations set forth in the Complaint and ensure that OTC drug products are not represented to be prescription drug products; and (3) correct the unapproved new drug violations set forth in the Complaint and ensure that their drug products are in strict conformity with applicable monographs or are the subject of approved new drug applications under 21 U.S.C. § 355(a) or investigational new drug applications under 21 U.S.C. § 355(i).

F. Within five (5) business days after receiving the expert's certification and report pursuant to subparagraphs 8(E)(i) and (ii), or as soon thereafter as is reasonably practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled, duly authorized FDA representatives make such inspections, as FDA deems necessary and without prior notice, of defendants' facilities, including buildings, equipment, finished and unfinished materials, containers, and labeling, and all records relating to the methods used in, and the facilities and controls used for, the manufacturing, processing, packing, labeling, holding, and distribution of drugs, to determine whether the requirements of this Decree have been met, and whether defendants' facilities are otherwise operating in compliance with CGMP, the regulations

including but not limited to the OTC monographs, and implementing the Act; and

G. FDA notifies defendants in writing that defendants appear to be in compliance with the requirements set forth in Paragraphs 8(A)-(E).

9. After defendants receive written notice from FDA pursuant to Paragraph 8(G) that they appear to be in compliance with Paragraphs 8(A)-(E) of this Decree, defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, any article of drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); or

B. Violates 21 U.S.C. § 331(k) by causing any article of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), after shipment of one or more of its components in interstate commerce;

C. Violates 21 U.S.C. § 331(a), by introducing and

causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded under 21 U.S.C. § 353(b)(4)(B), in that they are not prescription drugs within the meaning of 21 U.S.C. 353(b)(1) but bear the symbol "Rx Only";

D. Violates 21 U.S.C. 331(k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B); or

E. Violates 21 U.S.C. § 331(d) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

10. After defendants have complied with Paragraphs 8(A)-(E) and FDA has notified them pursuant to Paragraph 8(G), defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of their drug manufacturing operations not less than once every six (6) months for a period of three (3) years and not less than once every twelve (12) months for a period of one (1) year thereafter. If

defendants choose, the auditor may be the same person or persons retained as the expert in Paragraph 8(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the "audit report") analyzing whether defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspections are completed. In addition, defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any audit report observations, defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies defendants that a shorter time period is necessary. If, after receiving the audit report, defendants believe that correction of the deviations will take longer than thirty (30) calendar days, defendants shall, within twenty (20) calendar days of receipt of the audit report, propose a schedule

for completing corrections ("correction schedule"). That correction schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of defendants' receipt of an audit report, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by defendants, the expert, the auditor, or any other information, that defendants have failed to comply with any provision of this Decree, or have violated the Act, its implementing regulations, or CGMP, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act or CGMP, FDA may, as and when it deems necessary, order defendants in writing to take appropriate action, including, but not limited to, one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, and distributing any or all drug(s);

B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall specified drug products released or distributed by defendants or that are under the custody and control of defendants' agents, distributors, customers, or consumers. Defendants shall bear the costs of such recall(s); and/or

E. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring defendants into compliance with the Act, its implementing regulations, CGMP, or this Decree.

12. Any order issued pursuant to paragraph 11 shall issue from the Director, Florida District Office and shall specify the deficiencies or violations giving rise to the order.

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving an order pursuant to paragraph 11, defendants shall notify FDA in writing either that (1) defendants are undertaking or have undertaken corrective action, in which event defendants also shall describe the specific action taken or to be taken and the schedule for completing the action; or (2) defendants do not agree with FDA's order.

B. If defendants notify FDA that they do not agree

with FDA's order, defendants shall explain in writing the basis for their disagreement; in so doing, defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

C. If defendants advise FDA in writing that they do not agree with FDA's order, FDA will review defendants' written material and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable).

13. Any cessation of operations pursuant to paragraph 11 shall continue until FDA notifies defendants in writing that defendants appear to be in compliance with the Act, its implementing regulations, CGMP, and the requirements of this Decree, and that defendants may, therefore, resume operations.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of defendants' places of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings;

to take samples of defendants' finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all drug products, including components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate defendants' compliance with this Decree. The costs of such inspections shall be borne by defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $69.37 per hour and fraction thereof per representative for inspection work; $83.15 per hour or fraction thereof per representative for analytical or review work; $0.385 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the

event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. Within ten (10) calendar days after the entry of this Decree, defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, and post a copy of this Decree in the employee common areas at their manufacturing facilities. Within thirty (30) calendar days of the date of entry of this Decree, defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

17. Defendants shall notify FDA at least fifteen (15) calendar days before any change in ownership or character of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of Propharma, Inc., or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree.

Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

18. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

19. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

20. Defendants shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree shall be reviewed by the Court, if necessary, under the arbitrary and capricious standard, 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

21. This Court retains jurisdiction of this action for the

purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

22. No sooner than five (5) years after entry of this Decree, defendants may petition this Court for an order dissolving this Decree. If defendants have maintained to FDA's satisfaction a state of continuous compliance with this Decree, the Act, and all applicable regulations during the five (5) years preceding defendants' petition, plaintiff will not oppose such petition.

23. Defendants agree that during the term of this Decree, Mr. Steven J. Tunks will have no responsibilities that impact Propharma's CGMP compliance, either as an employee or consultant.

Dated this 23 day of November, 2004.

IT IS SO ORDERED:

UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

VICTOR G. FARINAS
on behalf of
Propharma, Inc.

VICTOR G. FARINAS,
in his individual capacity

FOR PLAINTIFF

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United States District Court

Southern District of Florida

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Notice of Orders or Judgments

Date: 11/24/04

To: Ann Marie St. Peter-Griffith (aty)
99 NE 4 Street
Miami, FL 33132

Re: Case Number: 1:04-cv-22933 Document Number: 3

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Number of pages including cover sheet: 18